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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,749	06/11/2001	Jacob Richter	2390/50002	2906

26646 7590 04/20/2005

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EXAMINER	
PANTUCK, BRADFORD C	
ART UNIT	**PAPER NUMBER**
3731	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	09/878,749	RICHTER, JACOB	
	Examiner	Art Unit	
	Bradford C Pantuck	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 22-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *03-10-2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-12 and 22-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,358, 487 to Miller in view of U.S. Patent No. 6,419,685 B2 to DiCaprio et al. Regarding Claims 1, 11, 23, and 31, Miller discloses an inner balloon and an outer balloon, as set forth by Applicant. One knows that the burst strength of the outer balloon is greater than that of the inner balloon because Miller explains that the inner balloon will burst and the outer balloon will contain the pressure and will be capable of receiving even more pressure [Column 3 line 64 to Column 4 line 5; see Fig. 2]. Miller does not disclose using his balloon catheter to deliver a stent, but DiCaprio uses a very similar device to deliver a stent of the same proportions recited by Applicant. DiCaprio teaches that delivering a stent with a balloon catheter is well known in the art [Column 1, lines 37-42] and therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Miller's balloon catheter to deliver a stent to an interior body lumen, as exemplified and taught by DiCaprio.

The inner balloon of the modified Miller balloon catheter will expand sufficiently to expand the middle portion of the stent and implant the stent. Miller discloses a

first period of expansion (*before* the first balloon bursts) called a "first pressure/expansion gradient" and a second period of expansion (*after* the first balloon bursts) called a "second pressure/expansion gradient" [see column 1 lines 34-46]. Miller further explains, "the first pressure/expansion gradient may be of a particularly desirable range to crack a hard stenosis in an artery as the inner balloon expands" [column 1, lines 44-48]. Examiner maintains that *if the inner balloon expands with sufficient force and diameter to crack a hard stenosis [all before bursting], then such a force/diameter would be sufficient to apply a stent to such a region in an artery.*

2. Regarding claims 2-6, 12, 24-26, and 32, although the specific burst pressures claimed by the applicant are not explicitly set forth by Miller or DiCaprio, it would have been an obvious matter of design choice to modify the respective balloons to have the claimed burst pressures, since applicant has not disclosed that the precise recited pressures provide any advantage, or solve a stated problem, or is used for any particular purpose. In other words, Examiner contends that the invention would *work equally well* if the respective burst pressures of the two balloons were 3 atmospheres and 6 atmospheres.

Alternatively, it is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to distinguish over the prior art. Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the

prior art, it possesses the authority to require the applicant to *prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.*

Finally, U.S. Patent No. 5,876,376 to Schwab et al. teaches that such pressure ranges are common for common angioplasty balloons [column 1, lines 26-35].

3. Regarding Claims 7-10 and 27-30, Miller discloses the use of several different materials to form the inner balloon and the outer balloon [column 3 lines 64-67], any of which can be considered relatively "compliant" or "non-compliant" relative to other materials.

4. Regarding Claim 22, Miller explains that after the inner balloon bursts, the outer balloon may be expanded further [column 2 lines 1-3]. Such an action would apply the stent of the modified Miller invention.

Conclusion

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory

period for reply expire later than SIX MONTHS from the mailing date of this final action.

Response to Arguments

6. Applicant's arguments, see "REMARKS", filed February 17, 2005, with respect to the rejection under 35 U.S.C. 102(e) with U.S. Patent No. 6,419,685 B2 to DiCaprio have been fully considered and are persuasive. Examiner agrees that DiCaprio teaches away from using inner balloon (116) to expand enough to be able to apply the stent (112), particularly in column 13, lines 44-50. Therefore, Examiner has withdrawn the rejection of the claims with this reference.

7. However, Applicant's arguments filed February 17, 2005 with regards to the rejection employing U.S. Patent No. 5,358, 487 to Miller in view of U.S. Patent No. 6,419,685 B2 to DiCaprio et al. have been fully considered but they are not persuasive. Applicant argues that there is no motivation for the combination of these references. Examiner disagrees. Miller teaches the use of his invention for angioplasty surgery [column 1, lines 1-3 and lines 23-24]. In Stedman's Medical Dictionary 27th Edition, angioplasty is defined as, "Reconstitution or recanalization of a blood vessel (blood vessel); may involve balloon dilation, mechanical stripping of intima, forceful injection of fibrinolytics, or *placement of a stent"* [emphasis added by Examiner]. Therefore, although Miller does not specifically mention using his device to deliver stents to the body, such a procedure would certainly not be outside the realm of possibility of the intended use. DiCaprio specifically teaches that during angioplasty [column 1, lines 51-53] one should use a balloon catheter *to deliver a*

stent in order to prevent restenosis and strengthen a portion of an artery [column 1, lines 54-60]. Examiner maintains that he has established a prima facie obviousness case.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP

BCP
April 18, 2005

ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
4/18/05